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EXAMINER

CRIARES, THEODORE J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,006

Applicant(s)

INPANBUTR, NONGNUCH

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15-17 and 19-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-17 and 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

CLAIMS 13, 15-17 AND 19-34 ARE PRESENTED FOR

EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.117(e) had been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2003 has been entered with the following effect:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-17 and 19-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach that dog food comprising "a proteinaceous component, and "a farinaceous component" as set forth in claims 13 and 33. Claims 15-17 and 19 32 and 34 which depend on claims 13 and 33 are therefore rejected under 35 USC § 112 *first paragraph*. This is considered new matter. A review of applicant's data fails to teach the claimed composition or an improvement over the prior art by placing the vitamin in proteinaceous and farinaceous components in dog food.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Applicant's claims are drawn to a composition containing Vitamin D analogues in dog food. The following rejection is based upon the claims as presently drawn, but excluding the new matter.

Claims 13, 15, 16, 23 and 30 to 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Boggolini et al. (5,087,619).

Boggolini et al. teach a composition comprising an effective amount of a Vitamin D₃ analogues, e.g., 1,25-(OH)D₃ and 1-alpha, 25 dihydroxy-delta-16,23-yne D₃ employed in a method of treating neoplastic diseases in a warm-blooded animal, see for example tables III and IV, claim 20 and abstract. Boggolini et al. also teach Vitamin D₃ analogues in oral dosage forms such as capsules, see Column 21, lines 37 to 40. Pharmaceutically acceptable carrier materials may be incorporated in capsules, such as starch, magnesium stearate, lactose, peppermint oil (flavoring agent), see in particular Column 21, line 37 to Column 22, line 27. Boggolini et al. also teach that the dosage for the Vitamin D₃ analogues is 0.1 to 10 microgram per day, see column 11, lines 16-24.

Claim Rejections - 35 USC § 103

Claims 13, 14-17 and 19-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boggolini et al. and Yu et al. (PMID 775663).

Boggolini et al., as set forth above teach a composition comprising an effective amount of a Vitamin D₃ analogue employed in a method of treating neoplastic diseases

by oral administration to a warm blooded animal. Pharmaceutically acceptable carrier materials may be incorporated in the composition as set forth above. Yu et al teach that EB 1089 is known to inhibit cell proliferation and is useful against neoplastic diseases, see abstract.

Boggolini et al. and Yu et al taken together do not teach the doses claimed herein in terms of nmol/Kg, neither do they teach all the pharmaceutical excipients and auxiliaries claimed herein. However, to one of ordinary skill in the art at the time the invention was made to employ/express the amounts of active in terms of nmol/Kg. It would have also been obvious to employ any known pharmaceutical excipients and auxiliaries in the composition employed in the instant composition. As stated in the Office Action of June 3, 2003.

Claims 24-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boggolini et al. and Yu et al in view of Katzung and Hardman et al.

Boggolini et al. teach the composition as set forth above. Applicant's claims 24-29, 33 and 34 include a second active agent, i.e., bone agent, cytotoxic agent or anti-inflammatory agent, in the composition of claim 13.

One of ordinary skill in the art would have been motivated to include these claimed known agents since Katzung teaches that hypercalcemia is a consequence of Hypervitaminosis D. This reference further teaches that bisphosphonates, calcitonin are employed in treating hypercalcemia, see pages 661-663. Katzung also teaches the employment of estrogen inhibitors at page 838-841 and anti-cancer agents cisplatin and NASIDS at page 537-538.

Hardman et al teach that pain is commonly associated with cancer, see page 539. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a second known active agent in the composition to treat cancer.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960).

As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art. "

In this application it would have been prima facie obvious to combine the claimed active agent to treat cancer in a dog and form the claimed composition. The preamble does not modify the claimed composition and is not considered in this rejection under 35 USC 103(a).


The rejections set forth in the Office Action of June 3, 2003 are incorporated herein..

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Criares
Primary Examiner
Art Unit 1617

tjc
3/31/04